DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 25, 2015

Terumo Europe N.V.
Mrs. M. J. Aerts
Regulatory Affairs Manager
Interleuvenlaan 40
3001 Leuven
BELGIUM

Re: K151398
Trade/Device Name: K- Pack II Needles- 29 G x 5/16" Thin Wall
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: May 21, 2015
Received: May 26, 2015

Dear Mrs. Aerts:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K151398

Device Name: K-Pack II Needle - 29G x 5/16" Thin Wall

Indication For Use:

The 29G x 5/16" Thin Wall K-Pack II Needle being a Hypodermic Single Lumen Needle is a sterile medical device for single use, intended to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin.

Prescription Use ___X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) SUMMARY as required by 807.92

Submitter information

Prepared for:	**TERUMO EUROPE N.V.** **Interleuvenlaan 40,** **3001 Leuven,** **BELGIUM**
Prepared by/Contact person:	**Mrs. M.J. Aerts – Manager Regulatory Affairs** **Tel. (+32) 16 38 13 53** **Fax (+32) 16 40 02 49**
Date prepared:	**May 2015**

II.1. Device Name

Proprietary Name

K-Pack II Needle - 29G x 5/16" Thin Wall

Classification Name

Hypodermic Single Lumen Needle

21CFR, Section 880.5570

Classification: Class II

Product Code

FMI

II.2. Predicate Devices

The following cleared devices are selected as predicate devices:

1. K-Pack II Needles (K984576)
2. 29G x ½" Thin Wall K-Pack II Needles (K082820)

II.3. Reason for Submission

This 510k is being submitted to extend the cleared K-Pack II Needle (K984576) product line with the K-Pack II Needle - 29G x 5/16" Thin Wall.

The 29G Thin Wall K-Pack II Needle is the same needle as the cleared 29G Thin Wall Needle covered in K082820, the only difference is that the needle length of the 29G x 5/16" Thin Wall K-Pack II Needle is shorter than what is currently cleared under the 29G x ½" Thin Wall Needle K082820.

The packaging of the 29G x 5/16" Thin Wall K-Pack II Needle in a short case is the same as the packaging of the cleared 29G x ½" Thin Wall K-Pack II Needle covered in K082820.

Although there are no potential issues of safety and effectiveness for a shorter length needle, this Special 510k is being submitted due to the fact that the new length is out of the range of the previously cleared needles.

This 510k will provide supporting information that the 29G x 5/16" Thin Wall K-Pack II Needles are an acceptable extension of the current K-Pack II Needle product line.

II.4. Intended Use

The 29G x 5/16" Thin Wall K-Pack II Needles being Hypodermic Single Lumen Needles are sterile medical devices for single use, intended to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin.

Note: This is the same intended use as the predicate devices, K-Pack II Needle - K984576 and 29G x ½" Thin Wall K-Pack II Needle K082820.

II.5. Substantial Equivalence

The 29G x 5/16" Thin Wall K-Pack II Needles are substantially equivalent in intended use, design, technology/principles of operation, materials, and performance to the following cleared devices:

1. K-Pack II Needles (K984576)
2. 29G x ½" Thin Wall K-Pack II Needles (K082820)

Differences between the devices do not raise any significant issues of safety and effectiveness.

The similarities and differences are summarized in the table below.

	29G x 5/16" Thin Wall K-Pack II Needle (Terumo Europe, Belgium) (Subject of this 510k)	29G x ½" Thin Wall K-Pack II Needles (Terumo Europe, Belgium) (K082820)	K-Pack II Needles (Terumo Europe, Belgium) (K984576)
Intended Use	Same as predicate	Intended to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin.	Intended to inject fluids into, or withdraw fluids from, parts of the body below the surface of the skin.
Materials	Same as predicate		
Cannula	Stainless Steel	Stainless Steel	Stainless Steel
Hub	Polypropylene	Polypropylene	Polypropylene
Glue	Epoxy glue	Epoxy glue	Epoxy glue
Lubricant	Silicone	Silicone	Silicone
Description/ Specifications	Same as predicate	Comprised of a stainless steel tube that is sharpened at one end and at the other end joined to a female luer connector (hub) designed to be connected with a male connector (nozzle) of a piston syringe.	Comprised of a stainless steel tube that is sharpened at one end and at the other end joined to a female luer connector (hub) designed to be connected with a male connector (nozzle) of a piston syringe.
Needle Gauge/ length	29G x 5/16"	29G x ½"	Ranging from 18G – 27G 3/8" – 1 ½"
Principle of Operation	Same as predicate	Manually	Manually

Unit packaging	Hard pack consisting of cap and short case	Hard pack consisting of cap and short case	Hard pack consisting of cap and long or short case
Wall Thickness	Thin Wall	Thin wall	Ultra thin + thin + regular wall
Sterilization	EtO to SAL 10^{-6}	EtO to SAL 10^{-6}	EtO to SAL 10^{-6}
Shelf life	5 years	5 years	5 years

II.6. Summary of Verification Activities

Design verification activities were conducted for the 29G x 5/16" Thin Wall K-Pack II Needles to demonstrate substantial equivalence to the predicate devices. This is for confirmation purpose only.

Summary of the verification activities including acceptance criteria is given in the table below:

TEST	ACCEPTANCE CRITERIA
1. Visual appearance	Silicon amount on cannula not visible as droplets.
2. Limits for acidity or alkalinity	Δ pH for K-Pack Needles extract solution is within 1 unit of the control fluid.
3. Limits for extractable metals	The extract solution of the 29G K-Pack II Needles has a content of extractable metals which is, when corrected for the metal content of the control fluid: Σ Pb, Sn, Zn, Fe ≤ 5 mg/l Cd < 0. 1 mg/l
4. Needle Penetration Resistance	The penetration resistance of cannula point and drag complies with the limits specified as follow: Point value ≤ 0.10 N and Drag Value ≤ 0.04 N
5. Conical fitting	The taper of the hub meets the gauging requirements of ISO 594-1.
6. Fitting strength hub/case	The force to pull axially the needle hub from the case is minimum 0.5 N and maximum 25 N.
7. Effective needle length	The effective length = nominal length + 1 mm/-2 mm.
8. Silicon amount on cannula	Needles are uniformly lubricated and the silicone is not visible as droplets on the outside surface of the needle, the quantity will not exceed 0.25 mg/cm^2.
9. Resistance to breakage	The cannula does not break when tested in accordance with EN ISO 9626.
10. Stiffness test cannula	The cannula shall show a deflection not greater than 0.37 mm in accordance with EN ISO 9626.
11. Corrosion Resistance (cannula)	The cannula shall show no signs of corrosion caused by the immersion in a sodium chloride solution 0.5 M.
12.Bonding strength between hub and cannula	The bonding strength between hub and cannula is ≥ 22N.
13. Liquid leakage	There is no leak of liquid at the luer (lock) fitting when the needle hub is fixed to reference control fitting in accordance with to ISO 594-1 and ISO 594-2.
14. Air leakage	There is no air leakage at luer (lock) fitting when the needle hub is fixed to a reference control fitting in accordance with to ISO 594-1 and ISO 594-2.

15. Flow rate	Tolerance on flow rate: between 80% and 125% of nominal value.
16. Torque Force Cap-Case	The torque force required to break the label and to remove the cap from the case is not more than 25 N.cm.
17. Endotoxin reaction	The device is free from endotoxin reaction in accordance with European Pharm. 2.6.14.
18. Abnormal toxicity	The device is free from abnormal toxicity in accordance with European Pharm. 2.6.9.
19. Sterility	The device is sterile in accordance with European Pharm. 2.6.1.

II.7. Additional Information

The sterility of the 29G x 5/16" Thin Wall K-Pack II Needles is assured by using a validated sterilization method qualified in accordance with EN ISO 11135-1: "Sterilization of Health Care Products – Ethylene oxide – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices", to a sterility assurance level (SAL) of 10^{-6} as required by EN 556-1: "Sterilization of Medical Devices - Requirements for medical devices to be designated "STERILE" - Part - 1: Requirements for terminally sterilized medical devices".

Ethylene oxide residual levels resulting from EtO sterilization are in compliance with EN ISO 10993-7: "Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals".

The 29G x 5/16" Thin Wall K-Pack II Needle, like the standard K-Pack II Needle (K984576), is an Externally Communicating device, Contacting Circulating Blood, Limited Exposure (≤ 24 hrs). The device's blood contacting materials were tested in accordance with the tests recommended in the FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard ISO-10993-1, "Biological Evaluation of Medical Devices Part-1: Evaluation and testing".

The expiration dating for the 29G x 5/16" Thin Wall K-Pack II Needles has been established at 5 years which is the same as the cleared K-Pack II Needles.

II.8. Conclusion

In summary, the 29G x 5/16" Thin Wall K-Pack II Needles are substantially equivalent in intended use, design, technology/principal of operation, materials, and performance to the following cleared devices:

1. K-Pack II Needles (K984576)
2. 29G x ½" Thin Wall K-Pack II Needles (K082820)

Differences between the devices do not raise any new issues of safety or effectiveness.